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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,572	06/12/2001	Arlene I. Ramsingh	0189-2001	4742

7590

08/28/2002

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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/28/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/879,572

Applicant(s)

RAMSINGH ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1648

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, insofar as drawn to recombinant attenuated JVB coxsackievirus B4 virions that express a heterologous polypeptide, classified in class 435, subclass 320.1.
- II. Claims 1 and 3-12, insofar as drawn to recombinant attenuated CB4-P coxsackievirus B4 virions in which a heterologous polypeptide is expressed as an internal fusion of VP1, classified in class 435, subclass 320.1.
- III. Claims 1, 3-6, and 13-17, insofar as drawn to recombinant attenuated CB4-P coxsackievirus B4 virions in which a heterologous polypeptide is expressed as an amino-terminal fusion of the viral polyprotein, classified in class 435, subclass 320.1.
- IV. Claims 18 and 19, insofar as drawn to a nucleic acid encoding the genome of a recombinant attenuated coxsackievirus B4 JVB that encodes a heterologous polypeptide, classified in class 536, subclass 23.4, e.g.
- ~ V. Claims 18, 20-27, and 30-36, insofar as drawn to a nucleic acid encoding the genome of a recombinant coxsackievirus B4 and a heterologous polypeptide expressed as an internal fusion of VP1, classified in class 536, subclass 23.4, e.g.
- VI. Claims 18, 20-23, 28, and 29, insofar as drawn to a nucleic acid encoding the genome of a recombinant coxsackievirus B4 and a heterologous

polypeptide expressed as an amino-terminal fusion of the viral polyprotein, classified in class 536, subclass 23.4, e.g.

- VII. Claims 37-40 and 43-51, insofar as drawn to method of inducing an immune response to a polypeptide comprising administering a recombinant coxsackievirus B4 virion that expresses a heterologous polypeptide as an internal fusion of VP1, classified in class 424, subclass 93.2, e.g.
- VIII. Claims 37, 38, and 40-51, insofar as drawn to method of inducing an immune response to a polypeptide comprising administering a recombinant coxsackievirus B4 virion that expresses a heterologous polypeptide as an amino-terminal fusion of the viral polypeptide, classified in class 424, subclass 93.2, e.g.
- IX. Claim 52, drawn to a method of immunizing against coxsackievirus infection, classified in class 424, subclass 216.1.
- X. Claim 53, drawn to a method of delivering a polypeptide, classified in class 514, subclass 44, e.g.

The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I, II, III, IV, V, and VI are distinct products that have different chemical and/or structural and/or immunological properties.

The nucleic acids of Inventions IV, V, and VI have different uses than in constructing the virions of Inventions I, II, and III, where Inventions II and III are used in

Art Unit: 1648

the methods of VII, VIII, and X as set out below, such as in the *in vitro* production of coxsackievirus proteins.

Inventions II and VII; III and VIII; and III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can each be used for affinity purification of antibodies to coxsackievirus or in assays for viral receptors.

The methods of Inventions VII, VIII, IX and X are patentably distinct methods that require different products and/or have different goals and outcomes.

The method of Invention VII does not require use of the product of Inventions I, III or IV.

The method of Invention VIII does not require use of the product of Inventions I, II or IV.

The method of Invention IX does not require use of the product of Inventions I, II, III, IV, V, or VI.

The method of Invention X does not require the product of Inventions I, II, IV, or V.

Because these inventions are distinct for the reasons given above because each group requires a search that is not coextensive with the search for any other group, restriction for examination purposes as indicated is proper.

Art Unit: 1648

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
August 27, 2002